FDA – Industry MDUFA V Reauthorization Meeting
July 21, 2021, 12:30 pm – 4:37 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Hanah Pham, *CDRH*
- Ron Yustein, *CDRH*
- Daniel Caños, *CDRH*
- Felipe Aguel, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pfleger, *Alcon*
- Danelle Miller, *Roche*
- Nicole Taylor Smith, *Medtronic*

MITA Team

- Peter Weems, *MITA*
- Diane Wurzburger, *GE Healthcare*
- Elisabeth George, *Philips*
- Nicole Zuk, *Siemens Healthineers*

MDMA Team

- Mark Leahey, *MDMA*
- John Manthei, *Latham & Watkins*
- Mark Gordon, *Alcon*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic Laboratories*

Meeting Start Time: 12:30 pm EST

Executive Summary

During the July 21, 2021 user fee negotiation meeting, Industry presented proposals on how to use the current carryover which included hiring additional staff, a financial assessment, and a

TAP pilot project. FDA presented on proposals related to the Patient Science & Engagement Program and Device Safety. FDA also shared an overview of Digital Transformation activities.

Industry's Presentation

Industry began its presentation by reviewing the principles underlying the MDUFA user fee program: 1) Supporting timely patient access to safe and effective medical devices, and to maintain the U.S. review process as the gold standard in the world for patient safety; 2) That Congressional appropriations remain the primary source of funding for the device review program; 3) That user fees are used solely for the premarket review process and are used for agreed purposes, while Industry is supportive of additional general appropriations for patient safety as well as other appropriate postmarket initiatives; 4) Recognition that Industry has made significant and material investments in building up the program through MDUFA I through IV, such that there has been a sizable growth in resources and the program is now on very stable footing; and, 5) That user fees should support mutually shared goals and process improvements to help achieve timely patient access to safe and effective devices.

Industry presented its detailed proposal for use of the available carryover balance of approximately $209M. The first aspect of the recommendations was to use a portion of these funds to hire 50 additional reviewers, which the carryover balance would cover through the entirety of the MDUFA V funding period; these reviewer hires would be in addition to existing vacancies. These reviewers would be assigned to review divisions based on workload, to enhance reviews and the review process specifically, including Pre-submission workload. Industry confirmed that the cost per FTE for these reviewers would be calculated based on the cost per FTE otherwise agreed upon for MDUFA V. Hiring for these positions could start immediately, given they are funded through existing carryover funds; hiring would not need to wait until the beginning of MDUFA V. This would represent a use of the funds for fundamental MDUFA funding and is the biggest component of the proposal.

The second aspect of Industry's proposed use of carryover balance was to hire six additional supervisors for oversight of additional reviewers. As with the proposed hiring of additional reviewers, these would be in addition to existing vacancies, hiring could begin in MDUFA IV, and the carryover balance would be able to fund these positions through the entirety of the MDUFA V funding period. Supervisors would be assigned to review divisions based on workload, and their additions would support the MDUFA IV commitment to include justifications in AI/deficiency letters.

Third, Industry proposed reserving part of the available carryover balance, $25M, as a "rainy day" fund to address unique or unexpected circumstances that threaten to disrupt the submission and review process. These circumstances might include a government shutdown, with the funds being used to help maintain reviewers and premarket review activity; it could relate to some type of emergency situation; or, it could be used for an unexpected or acute surge in device submissions. Over the history of MDUFA, there have been various steps taken to address capacity and workload, such as broadening the base of fees to better reflect workload and to have a more predictable base of fees, and then the elimination of the fifth-year offset provision in MDUFA IV. Industry reiterated that it had some concerns about FDA's proposed workload adjuster mechanism, and suggested that this alternative would help address acute situations of

workload spikes or other disruptions. Industry anticipated that while general parameters for use of the fund would be developed, the ultimate mechanism for using the funds would be for FDA to notify Industry, in a quarterly meeting or otherwise, of a need to use these funds, and obtain Industry's concurrence.

Next, Industry proposed using part of the available carryover balance to fund an independent assessment of human resources, including to evaluate time reporting and an appropriate metric for a full-time equivalent (FTE) unit for purpose of measuring workload.

Finally, although Industry did not support the TAP program as initially proposed by FDA, Industry indicated willingness to fund a small pilot program that would allow for a proof of concept of a premarket advisory program, to evaluate whether and how it would work and what its benefits would be. Industry stressed that objective measures are required to clearly demonstrate the feasibility of the TAP program.

With regard to remaining available carryover balance, after these initiatives are accounted for, Industry proposed that such remainder should be used based on discussion and concurrence with Industry, and could be used in part to offset MDUFA V costs overall if necessary.

Industry provided additional elaboration on its proposed parameters for testing out a proof of concept for a premarket advisory program on a pilot basis. Industry reiterated the questions and concerns previously raised about the TAP program, which could be assessed in establishing and carrying out a small pilot program. These include uncertainty about statutory authority to carry out the substance of this program and to fund it through user fees; whether external stakeholders (e.g., CMS and private payors) are willing and able to collaborate in this program; whether there are people that have the cross-functional expertise to serve in the TAP advisor roles; that the TAP advisors are not contemplated to be embedded with the review team and their feedback may not reflect the view of the review division; the lack of identified goals or metrics for success; the relevance of this program to the vast majority of devices; and finally, the potential resources involved in scaling such a program. Industry suggested that these questions and issues could be better evaluated based on a small proof of concept, to determine if such a program would have sufficient value and would be supported by enough of the industry to pursue further. Industry recommended that a pilot start during MDUFA IV (given its proposal to fund the pilot with carryover balance funds).

Industry identified several prerequisites to be confirmed before agreeing to a proof of concept pilot—notably, confirmation that FDA has sufficient statutory authority to conduct the pilot, in terms of substantive authority and the use of user fee funds, that there is confirmation from CMS and private payors that they are willing and able to collaborate pursuant to the pilot, and assurance that participation would be voluntary.

In order to assess the pilot, Industry recommended several reporting and evaluation steps. First, FDA would issue a report by the end of FY 2025 detailing the timeline, and steps in the process, for the devices in the pilot. Industry recognized that participants would need to work with FDA on sharing appropriate details, which would be context-specific, with confidential information subject to redaction. Separately, a third-party independent report would gather informal feedback

from participants and provide an assessment and recommendations for appropriate accountability and success measures, as well as a financial assessment. Finally, FDA would provide quarterly updates on pilot program financing, with a close-out report at the end of the pilot reviewing the financing, analyzing other existing programs with similar objectives, and describing any additional statutory authority that would be helpful if such a program were to be permanently implemented.

FDA Presentation

FDA opened the second half of the meeting by reviewing the Agency's goals for the MDUFA negotiation: (1) To enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; (2) To improve device safety across the total product lifecycle; and (3) To optimize FDA infrastructure, staffing, and resources to keep pace with scientific development.

In particular, FDA's focus during the meeting included how MDUFA V could build on the success of the patient science and engagement program, and continuing the discussion on how MDUFA V could strengthen FDA's capability to more rapidly evaluate and resolve potential safety issues.

Patient Science & Engagement

FDA shared an update on how the Patient Science & Engagement (PSE) program met and exceeded the MDUFA IV commitments. Successes included building FDA's capacity to expertly review patient science, cultivating predictability and transparency by publicly disseminating learnings, advancing patient science research, and fostering patient engagement. The PSE Program hired staff which provide frequent consultations on total product lifecycle (TPLC) reviews, training for FDA staff, and engagement with external stakeholders. The staff also support the conduct of patient preference studies and assist in the qualification of Medical Device Development Tools in patient science.

FDA proposed three mechanisms to expand the PSE Program during MDUFA V:

(1) FDA proposed a Patient Engagement Incubator to establish a curriculum to train patients to collaborate in medical device research as advisors in clinical trials, medical device tool development and evaluation, and TPLC data collection efforts. Patient advisors would be external to FDA and would be a resource to provide input across the TPLC. FDA would target outreach to diverse patient populations through strategic partnerships, and the Agency would maintain continuous learning opportunities to keep the knowledge contemporary and relevant.

(2) FDA proposed a Patient Science Evidence Accelerator to generate evidence supporting the use of patient preference information (PPI), patient-generated health data, and clinical outcome assessments as primary or complementary data for regulatory submissions. For instance, as part of this work, FDA would generate evidence to adapt or leverage clinical outcome assessments for different demographic groups, new medical conditions, or with new technologies. The Agency also would facilitate the conduct of patient preference studies in preference sensitive areas to inform medical device development and evaluation. FDA also would continue the

ongoing review of patient science in submissions, deliver internal training, and continue to advance development of guidance in this area.

(3) FDA proposed to establish a Shared Decision-Making Team to focus on developing and collaborating on shared decision aids to support informed decision-making by patients and clinicians. This work would expand consumer education regarding the benefits and risks of devices to help empower patient decision-making.

Device Safety

FDA presented additional details on its device safety proposal within four areas of focus:

(1) FDA proposed that user fee resources could help enable the Agency's timely access to high quality post-market information from US-based and international data sources. FDA noted that timely access to high quality data would allow for more accurate and efficient signal refinement.

(2) FDA proposed that user fee resources could help expand the Agency's analytic capabilities and understanding of how real-world evidence (RWE) can be used to evaluate potential device safety issues. In addition to growing the Agency's bench strength to more rapidly evaluate potential signals, these resources could help enable identification of best practices and principles for the design and evaluation of post-market safety RWE-based studies.

(3) FDA proposed that user fee resources could help expand the Agency's review team expertise to support device safety evaluation and the development and implementation of safety mitigations. Additional resources within premarket review offices could allow for increased focus on collecting and analyzing safety information across the TPLC, and they could help improve consistency in approach across reviewing offices as well as increased transparency to industry and the public, such as through guidance.

(4) FDA proposed that user fee resources could help support engagement and communication with clinical and patient communities on device safety. In addition to growing the Agency's expertise in risk communication and patient communication, the resources could help support efforts to communicate with industry, patients, and other interested stakeholders through product-safety focused workshops and the development of guidance documents. The resources could also support development and maintenance of an online repository of current device labeling and patient information to support clinical and patient decision-making.

Industry requested clarification for how this proposal overlaps with the activities performed by the NEST coordinating center (NESTcc). FDA explained that NESTcc is one source of data, and FDA sees opportunities in accessing a variety of data sources. Industry asserted that changes to FDA's statutory authority would be needed, and FDA asserted that the activities in the proposal are within FDA's existing authority, though the MDUFA statute would require updating to allow user fees to be used on some of the activities within the proposal. Industry expressed that while safety is a focus of FDA and Industry, MDUFA user fees are not authorized by statute for use for postmarket safety activities; that, in Industry's view, they should be funded by congressional appropriations rather than user fees; and that FDA has not requested such appropriations.

Update on Digital Transformation

FDA presented an overview of its Digital Transformation workstream, which will modernize CDRH's outdated and fragmented information technology (IT) infrastructure. FDA explained how Digital Transformation will streamline business processes to support more efficient and consistent submission review and improve communication with stakeholders. Once completed, Digital Transformation will, among other benefits, bring CDRH business processes closer to the speed of industry. It will improve the timeliness of delivery of services by creating one integrated environment for CDRH employees to find, integrate and analyze—using modern analytical and artificial intelligence tools—complete information, enabling more efficient and effective application processing. In addition to improving IT service delivery, Digital Transformation will also reduce IT costs.

As part of Digital Transformation, new platforms include the Customer Collaboration Portal, which will fulfill a MDUFA IV commitment and allow sponsors visibility into the progress of their submissions. The Decision Management Portal will provide a unified user experience for CDRH staff by making it easier to navigate the applications and find the information needed for their work. The Modern Analytics Platform will include comprehensive search and analytics features. The Centralized Enterprise Integration will facilitate consistent application of business rules, data access, and data entry.

FDA shared the cost estimates for Digital Transformation through FY 2024 stating that total costs through FY 2024 for Digital Transformation will total approximately $330 million, and noting that this effort is largely being funded by new money provided by Congress. Funds that CDRH accrued in the MDUFA carryover balance by spending a higher portion of budget authority on MDUFA costs between 2017-2020; savings realized by replacing costs that CDRH would have spent to maintain its existing, aging IT systems; and MDUFA user fees would provide additional funding.

Update on MDUFA Work Group Meetings

FDA and Industry reviewed a summary of two work group meetings:

On July 19, 2021, FDA and Industry met in a work group to discuss RWE. At FDA and Industry's invitation, the NESTcc had shared its vision for continuation of the NEST during MDUFA V. In addition, FDA had provided a readout of the Agency's work to enhance its RWE program during MDUFA IV.

On July 20, 2021, FDA and Industry met in a work group to discuss the Third Party Review (3PR) program and international harmonization. During the meeting, FDA had described enhancements to the 3PR program that were made during MDUFA IV, and the funds available in the carryover balance to continue the program during MDUFA V. FDA had also shared its initial thinking of how MDUFA could potentially support international harmonization efforts.

Meeting End Time: 4:37 pm EST